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EXAMINER

SMITH, TERRI L

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,421

Applicant(s)

BRODNICK, DONALD E.

Examiner

Terri L. Smith

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date January 11, 2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because reference numbers 21 and 26 both refer to a signal processor (Fig. 4, elements 22 and 26). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: The phrase “signal processor” is referenced by number 21 (page 7, lines 13, 14, 16, 18, and 24; page 8, lines 16, 19 and 30; page 10, line 8) and number 26 (page 8 lines 9 and 10; page 9, line 25; page 10, line 17).

Similarly, reference number 20 is identified as “acquisition module” (page 5, line 17; page 7, lines 2, 3, 10, 11, 13, 18, 26, and 28); page 8, line 3; page 9, line 23; page 10, lines 13 and 16) and “acquisition device” (page 10, lines 4 and 6). In the drawings reference number 20 is identified as “acquisition module” (Fig. 9, block 110 and Fig. 10, block 210).

Likewise, reference number 22 is identified as “transmitter” (page 5, line 17 and 22; page 8 lines 4 – 6 and 8; page 9, line 23) and “wireless transmitter” (page 8, line 3). In the drawings reference number 22 is identified as “transmitter” (Fig. 9, block 112).

On page 9, line 7, there is not a space between “PCT” and “where.”

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 5, 6, 15, 45, 49, 50, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Segalowitz, U.S. Patent 5,511,553.

Regarding Claims 1 and 45, Segalowitz discloses a plurality of electrodes (Fig. 8) for attachment to the patient's upper torso (Figs. 8 and 17), wherein a plurality of electrodes does not include electrodes for attachment to the patient's limbs; an acquisition module (Fig. 8, element 184; Fig. 17, element 361) coupled to a plurality of electrodes for acquiring electrical signals from the plurality of electrodes; and a signal processor (Fig. 8, element 186; Fig. 17, element

382; Fig. 21, element 401) coupled to an acquisition module for generating a plurality of electrocardiogram precordial leads from the acquired signals (Fig. 8, precordial leads $V_1 - V_6$).

Regarding Claims 5 and 49, Segalowitz discloses a signal processor generates a plurality of electrocardiogram precordial leads from the acquired electrical signals (column 27, lines 49 – 56, 64 – 66; column 28, line 1; column 35, lines 34 – 52) by generating an approximation of an electrical potential near the center of the patient's heart based on the acquired electrical signals (Fig. 17, element 321 with details of element 321 shown in Fig. 18; column 30, lines 57 – 58 and 60 – 62; column 31, lines 4 – 9).

Regarding Claims 6 and 50, Segalowitz discloses an approximation of an electrical potential near the center of the patient's heart is an approximation of Wilson's central terminal (column 30, lines 57 – 62). In view of a teaching on Wilson's terminal, Segalowitz teaches that the central terminal is the zero or reference point generally referred to as the central terminal (column 17, lines 63 – 67; column 18, lines 1 – 2).

Regarding Claims 15 and 59, Segalowitz discloses an electrocardiogram machine (Figs. 17 and 21, element 397) wirelessly coupled to the acquisition module (Figs. 17 and 21, elements 396) and a telemetry monitor (Figs. 17 and 21, element 398) coupled to the electrocardiogram machine (column 35, lines 53 – 59).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 – 4, 16, 30, 33 and 46 – 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segalowitz, and in view of Ricketts et al., U.S. Patent 4,026,278.

Regarding Claims 2, 16 (the portion covering the first two limitations of the device), 30 (the portion covering the first two limitations of the device), and 46, Segalowitz does not disclose a belt adapted to be attached around the circumference of the patient's upper torso, and wherein a plurality of electrodes are coupled to the belt so that when the belt is attached to the patient each one of the plurality of electrodes is generally positioned in a plane perpendicular to a longitudinal axis approximately defined by the patient's spine; a plurality of electrodes coupled to a belt, a plurality of electrodes including at least one electrode positioned within the belt so that when the belt is attached to the patient the electrode contacts the patient's chest, and at least one electrode positioned within the belt so that when the belt is attached to the patient the electrode contacts the patient's back, wherein the plurality of electrodes does not include electrodes for attachment to the patient's limbs (column 2, lines 45 – 46 and 53 – 56). However, Ricketts does disclose a belt adapted to be attached around the circumference of the patient's upper torso (Fig. 1), and wherein a plurality of electrodes are coupled to the belt (column 2, lines 45 – 46 and 53 - 56) so that when the belt is attached to the patient each one of the plurality of electrodes is generally positioned in a plane perpendicular to a longitudinal axis approximately defined by the patient's spine (Fig. 1) Ricketts also discloses a plurality of electrodes coupled to a belt, a plurality of electrodes including at least one electrode positioned within the belt so that when the belt is attached to the patient the electrode contacts the patient's chest, and at least one electrode positioned within the belt so that when the belt is attached to the patient the electrode

contacts the patient's back, wherein the plurality of electrodes does not include electrodes for attachment to the patient's limbs (column 2, lines 45 – 46 and 53 – 56) to provide an improved means for rapidly and securely applying electrodes to a body member (column 1, lines 39 – 41).

Regarding Claims 3 and 47, Segalowitz does not disclose a belt is adapted to be attached around the circumference of a patient's upper torso at a level slightly below the patient's breast. However, Ricketts discloses a belt is adapted to be attached around the circumference of a patient's upper torso at a level slightly below the patient's breast (Fig. 1) to provide an improved means for rapidly and securely applying electrodes to a body member (column 1, lines 39 – 41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Segalowitz to include a belt adaptable to be attached around the circumference of a patient's upper torso and at a level slightly below the patient's breast, such that a plurality of electrodes are coupled to the belt so that when the belt is attached to the patient each one of the plurality of electrodes is generally positioned in a plane perpendicular to a longitudinal axis approximately defined by the patient's spine, as taught by Ricketts, to provide an improved means for rapidly and securely applying electrodes to a body member (column 1, lines 39 – 41).

Regarding Claims 4, 16 (the portion covering the last four limitations of the device), 30 (the portion covering the last two limitations of the device), and 48, Segalowitz discloses a transmitter (Fig. 17, element 383) coupled to an acquisition module (Fig. 17, element 381) and a plurality of electrodes for acquiring electrical signals from a plurality of electrodes (Fig. 8, element 184); and a receiver (Fig. 17, element 388) coupled to an electrocardiogram machine (Fig. 17, elements 397 and 398), wherein a transmitter (Fig. 17, element 383), an acquisition

module (Fig. 17, element 381), and a signal processor for generating a plurality of electrocardiogram precordial leads from the acquired electrical signals (Fig. 17, element 382) are coupled to a belt (Fig. 17, element 321), wherein a receiver (Fig. 17, element 388) is coupled to an electrocardiogram machine (Fig. 17, element 397, 398), and wherein a plurality of electrocardiogram precordial leads are wirelessly transmitted from a transmitter to a receiver to a remote location (Fig. 17).

7. Claims 7, 14, 51, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segalowitz as applied to claims 1, 5, 45, and 49 above, and further in view of Shusterman et al., U.S. Patent 6,389,308.

Regarding Claims 7 and 51, Segalowitz does not disclose a signal processor generates an approximation of an electrical potential near the center of the patient's heart by determining a weighted combination of a plurality of the acquired electrical signals. However, Shusterman discloses a signal processor generates an approximation of an electrical potential near the center of the patient's heart by determining a weighted combination of a plurality of the acquired electrical signals (column 7, lines 48 – 50) to achieve the optimal sensitivity in the detection of hidden or small ECG changes (column 7, lines 40 – 41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Segalowitz to include a signal processor to generate an approximation of an electrical potential near the center of the patient's heart by determining a weighted combination of a plurality of the acquired electrical signals, as taught by Shusterman, to achieve the optimal sensitivity in the detection of hidden or small ECG changes (column 7,

lines 40 – 41).

Regarding Claims 14 and 58, Segalowitz does not disclose an acquisition module is capable of storing precordial leads for approximately one month. However, Shusterman discloses an acquisition module (Fig. 1) is capable of storing precordial leads for approximately one month (Fig. 13; column 5, lines 66 – 67) for focusing on a patient's critical primary elements (column 5, lines 16 – 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Segalowitz to include an acquisition module capable of storing precordial leads for approximately one month, as taught by Shusterman, for focusing on a patient's critical primary elements (column 5, lines 16 – 17).

8. Claims 8, 11, 12, 52, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segalowitz as applied to claims 1 and 45 above, and further in view of GE Medical Systems Information Technologies, *ACI-TIPT Standard 12/15 – Lead Placement*.

Regarding Claims 8 and 52, Segalowitz does not disclose a plurality of electrodes includes a first electrode attachable to the patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to the patient's chest in approximately the fifth intercostal space at the anterior axillary line, a third electrode attachable to the patient's back in approximately the fifth intercostal space under the left mid-scapular line, and a fourth electrode attachable to the patient's back in approximately the fifth intercostal space under the right mid-scapular line. However, the article by GE Medical Systems Information Technologies, *ACI-TIPT Standard 12/15 – Lead Placement*, teaches that a plurality of electrodes

includes a first electrode attachable to the patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to the patient's chest in approximately the fifth intercostal space at the anterior axillary line, a third electrode attachable to the patient's back in approximately the fifth intercostal space under the left mid-scapular line, and a fourth electrode attachable to the patient's back in approximately the fifth intercostal space under the right mid-scapular line (Figures on first and second pages) to provide guidelines for ECG placement to correctly determine ECG lead placement (first page).

Regarding Claims 11 and 55, Segalowitz does not disclose a plurality of electrodes includes a first electrode capable of being attachable to the patient's back in approximately the fifth intercostal space under the right mid-scapular line and at least one electrode attachable to the patient's chest. However, the article by GE Medical Systems Information Technologies, *ACI-TIPT Standard 12/15 – Lead Placement* discloses a plurality of electrodes includes a first electrode capable of being attachable to the patient's back in approximately the fifth intercostal space under the right mid-scapular line (first page) and at least one electrode attachable to the patient's chest (second page) to provide guidelines for ECG placement to correctly determine ECG lead placement (first page).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Segalowitz to include a plurality of electrodes that includes a first electrode attachable to the patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to the patient's chest in approximately the fifth intercostal space at the anterior axillary line, as taught by GE Medical Systems Information Technologies, to provide guidelines for ECG lead placement to correctly

determine ECG lead placement (first page).

Regarding Claims 12 and 56, Segalowitz discloses a signal processor uses a signal acquired from a first electrode (Fig. 18, element 363 on strip 321) as an approximation of an electrical potential near the center of the patient's heart (Fig. 17, element 321; column 31, lines 8 – 9).

9. Claims 9 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segalowitz and GE Medical Systems Information Technologies as applied to claims 8 and 52 above, and further in view of Shusterman, U.S. Patent 6,389,308.

Regarding Claims 9 and 53, neither Segalowitz nor GE Medical Systems Information Technologies disclose a signal processor generates an approximation of an electrical potential near the center of the patient's heart by determining a weighted combination of the signals acquired from a plurality of electrodes. However, Shusterman discloses a signal processor generates an approximation of an electrical potential near the center of the patient's heart by determining a weighted combination of the signals acquired from a plurality of electrodes (column 7, lines 48 – 50) to achieve the optimal sensitivity in the detection of hidden or small ECG changes (column 7, lines 40 – 41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Segalowitz to include a signal processor to generate an approximation of an electrical potential near the center of the patient's heart by determining a weighted combination of the signals acquired from a plurality of electrodes, as taught by Shusterman, to achieve the optimal sensitivity in the detection of hidden or small ECG changes (column 7, lines 40 – 41).

10. Claims 10 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segalowitz, GE Medical Systems Information Technologies, and Shusterman as applied to claims 9 and 53 above, and further in view of, Pritchard, U.S. Patent 5,615,687.

Regarding Claims 10, 24, 39, 54 and 67, Segalowitz nor GE Medical Systems Information Technologies nor Shusterman disclose a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of the patient's heart from each one of the signals acquired from a first electrode and a second electrode. However, Pritchard discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of the patient's heart from each one of the signals acquired from a first electrode and a second electrode (column 1, lines 59 – 62) to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44 – 46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Shusterman to include a signal processor to generate each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of the patient's heart from each one of the signals acquired from a first electrode and a second electrode, as taught by Pritchard, to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44 – 46).

11. Claims 13 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segalowitz, and GE Medical Systems Information Technologies as applied to claims 12 and 56 above, and further in view of, Pritchard, U.S. Patent 5,615,687.

Regarding Claims 13 and 57, Segalowitz and GE Medical Systems Information Technologies do not disclose a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of the patient's heart from each one of the signals acquired from the at least one electrode on the patient's chest. However, Pritchard discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of the patient's heart from each one of the signals acquired from the at least one electrode on the patient's chest (column 1, lines 59 – 62) to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44 – 46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Segalowitz to include a signal processor to generate each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of the patient's heart from each one of the signals acquired from the at least one electrode on the patient's chest, as taught by Pritchard, to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44 – 46).

12. Claims 60 and 71 rejected under 35 U.S.C. 103(a) as being unpatentable over Ricketts et al., U. S. Patent 4,026,278, and in view of Segalowitz et al., U.S. Patent 5,511,553 and Shusterman, U.S. Patent 6,389,308.

Regarding Claim 60, Ricketts discloses positioning a plurality of electrodes on the patient's upper torso, a plurality of electrodes including at least one electrode positionable on the patient's chest and at least one electrode positionable on the patient's back (Fig. 1; column 2, lines 45 – 46 and 53 – 56), wherein a plurality of electrodes does not include electrodes for positioning on the patient's limbs. However, Ricketts does not disclose acquiring electrical signals from a plurality of electrodes nor generating an approximation of an electrical potential near the center of the patient's heart by determining a weighted combination of a plurality of the acquired electrical signals and generating a plurality of electrocardiogram precordial leads from the acquired electrical signals by subtracting an approximation of the electrical potential near the center of the patient's heart from each one of the signals acquired from the at least one electrode on the patient's chest.

Nonetheless, Segalowitz discloses acquiring electrical signals from a plurality of electrodes (column 27, lines 49 – 56, 64 – 66; column 28, line 1; column 35, lines 34 – 52) to transmit a single encoded radio frequency signal which carries the twelve-lead electrocardiographic multiple heart signals (column 27, lines 65 – 67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Ricketts to include acquiring electrical signals from a plurality of electrodes, as taught by Segalowitz, to transmit a single encoded radio frequency signal which carries the twelve-lead electrocardiographic multiple heart signals (column 27, lines

65 – 67).

Shusterman discloses generating an approximation of an electrical potential near the center of the patient's heart by determining a weighted combination of a plurality of the acquired electrical signals; and generating a plurality of electrocardiogram precordial leads from the acquired electrical signals by subtracting an approximation of the electrical potential near the center of the patient's heart from each one of the signals acquired from the at least one electrode on the patient's chest (column 7, lines 48 – 50) to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44 – 46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Ricketts to generate a plurality of electrocardiogram precordial leads from the acquired electrical signals by subtracting an approximation of the electrical potential near the center of the patient's heart from each one of the signals acquired from the at least one electrode on the patient's chest., as taught by Shusterman, to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44 – 46).

Regarding Claim 71, Shusterman discloses the act of acquiring electrical signals from a plurality of electrodes (Fig. 1) includes the act of acquiring electrical signals for approximately one month (Fig. 13; column 5, lines 66 – 67).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The examiner can normally be reached on Monday – Friday between 7:30 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
February 16, 2005


GEORGE R. EVANISKO
PRIMARY EXAMINER

2/17/5